M. Girkel file



## THE ROCKEFELLER UNIVERSITY

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JOSHUA LEDERBERG

PRESIDENT

Dr. Marion Finkel
Associate Director for New
Drug Evaluation
Department of Health, Education
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Food and Drug Administration
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Dear Dr. Finkel:

It was a pleasure to have a chance to meet you at the Hoechst Symposium the other day. I'm sorry that you had to leave before we could continue a discussion on some of the topics that you introduced. I am not sure whether you have any more robust confidence than I in the adequacy of our present procedures for assessing risks like cancer, from animal experimentation as currently conducted. I feel rather gloomy about being able to develop socially optimized policies on regulation without a major intellectual reconstruction of toxicology as a scientific discipline; and this is not something that can be done overnight. Your plea that the companies be more energetic and candid in forwarding realistic risk-benefit analysis I did applaud. Meanwhile the obvious contemporary deterrents to vigorous and optimistic investment in pharmaceutical research of the most fundamental kind is simply leading many companies to pursue their profits by other routes -- and for the large ones this is not an obvious hindrance to their balance sheets.

But your slide of the number of inputs that you receive in the regulatory process is most impressive; and perhaps only a fool now dares to tread on such a well worked-over territory.

I was also intrigued by your reference to the discussion about indications for elective induction of pregnancy, about which I had heard only some vague rumor. Some years ago, I was quite interested in births by day of week and wondered

a) if I could find statistics on the frequency with which elective induction was practiced that could hope to account for the "Sunday effect"; b) whether there were other endogenous psychosomatic factors involved in the regulation of delivery time and c) whether there might be adverse effects on pregnancy outcome by the practice of elective induction. The latter is, of course, confounded by the fact that there will sometimes be specific medical indications for this practice that are bound to lead to some complications in that group. My recollection is a little fuzzy now about what further was done about this: I believe I had some conversations about using the NINDS perinatal morbidity study but to my present recollection nothing came out of it. If you can give me some pointers back into the mainstream of that discussion I would be appreciative of it.

I hope there may be some occasion for a more leisurely discussion of a number of subjects in which I am sure we share a deep mutual interest.

Yours sincerely,

oshua Lederberg

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